

## TITLE

Balloon Catheter with Striped Flexible Tip

## CROSS-REFERENCE TO RELATED APPLICATIONS

5 Not Applicable

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

## 10 BACKGROUND OF THE INVENTION

This invention relates to the field of intravascular medical devices, and more particularly to the field of catheters such as angioplasty, neurological and guide catheters, among others, which may be used in various medical procedures such as percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA) as  
15 well as in procedures involving the placement of medicines and medical devices within the body. The present invention is directed to all forms of catheters which may be advanced through a body lumen or vessel. Some examples of catheters are over-the-wire (OTW) catheters, such as are described in US 5047045; single-operator-exchange (SOE) balloon catheters, such as are described in US 5156594 and US 5549552. Other examples of  
20 catheters which may incorporate the unique features of the present invention are also described in US 5938653, US 5897537, among others.

The entire content of all of the patents listed within the present patent application are incorporated herein by reference.

Intravascular diseases are commonly treated by relatively non-invasive  
25 techniques such as PTA and PTCA. These angioplasty techniques typically involve the use of a balloon catheter. In these procedures, a balloon catheter is advanced through the vasculature of a patient such that the balloon is positioned proximate a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened. In other uses a catheter may be used to delivery an endoprosthesis such as a stent, graft, vena

*[Faint, illegible markings]*

5 other form of treatment catheter, to the portion of the vessel requiring treatment or inspection. The guide catheter is urged through the vasculature of the patient until its distal end is proximate the restriction. The balloon catheter may then be fed through a lumen in the guide catheter.

the use of a solitary dilatation or medical device delivery catheter, catheters typically must possess a level of rigidity which will allow it to traverse tortuous pathways through blood vessels in a manner that minimizes trauma. The catheter must be capable of being advanced through the vascular system without folding or buckling despite application of longitudinal and/or rotational forces upon the catheter. Because many catheters have the desired rigidity, it is desirable to incorporate a relatively flexible and desirably atraumatic tip on the distal end of the catheter to avoid injury to the walls of the blood vessels as the otherwise comparatively rigid catheter is advanced therethrough.

## BRIEF SUMMARY OF THE INVENTION

20                   The present invention provides a catheter with a novel tip or distal end which is sufficiently rigid to avoid kinking and bending as it advances through a lumen, but which is sufficiently soft and flexible such that the tip is less likely to cause trauma to vessel surfaces which it may contact.

The catheter tip may be provided with the desired characteristics by  
25 constructing the tip from a combination of at least two materials having different material  
characteristics such as hardness.

In at least one embodiment of the invention, the catheter tip comprises a first material or matrix and one or more stripes or segments of a second material, wherein the second material is harder than the first material.

The second material may be characterized as one or more stripes of material imbedded within or engaged to the first material. The stripes of material may be coextruded with the matrix or may be engaged to the matrix after formation of the first material. The stripes of the second material may be uniform in width along the length of the catheter tip.

15 Alternatively the stripes may taper, be intermittent, or otherwise configured. Furthermore, the stripes may be disposed about the matrix in a variety of ways, such as for example, one or more stripes may be helically wound about the tip, multiple stripes may be longitudinally parallel throughout the length of the tip, a stripe or stripes may extend along the length of the tip and taper toward or away from the end of the tip in increasing or decreasing width.

20 Other characteristics of the stripe or stripes of secondary material may also be varied relative to the first material matrix. For example, the second material may have a thickness equal to or different from the thickness of the first material.

The stripes of relatively hard secondary material may alternatively be characterized as one or more coatings applied to the surface of the first material.

25           The second material may also be characterized as one or more fibers or braids of fiber of a predetermined material or combination of materials. The fibers may be oriented relative to the longitudinal axis of the catheter tip in a variety of patterns. For example the fibers may be substantially parallel to the longitudinal axis of the sleeve, angled relative thereto, helically or otherwise disposed thereabout, etc.



FIG. 9 is a perspective view of another embodiment of the catheter tip of the present invention;

FIG. 10 is a perspective view of another embodiment of the catheter tip of the present invention;

5 FIG. 11 is a detailed partially cut-away view of another embodiment of the catheter tip of the present invention;

FIG. 12 is a cross-sectional view of another embodiment of the catheter tip of the present invention; and

10 Fig. 13 is a cross-sectional view of another embodiment of the catheter tip of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

In the various FIGs. 1-13 identical components are designated by the same reference numbers in the following description of various embodiments.

15 As may be seen in FIG. 1, the present invention may be embodied in a catheter, indicated generally at 10. Catheter 10, may be any type of catheter such as a balloon catheter, a stent delivery catheter, a guide catheter or other type. The catheter may have a fixed wire, OTW, rapid exchange or other type of configuration as desired. The catheter 10 has a body 12 consisting of a shaft 14 which extends distally to a distal end or tip 16. In many embodiments the catheter 10 may include an inflation member or balloon 18 disposed about the shaft 14 proximal to the distal tip 16. The inflation member may be configured to deliver or seat a medical device such as a stent and may be equipped with one or more stent retaining sleeves, such as is described in U.S. App. No. 09/829,295 to Yang, filed April 9, 2001, the entire contents of which being incorporated herein by reference.

25 As indicated above, catheter 10 may be any type of catheter capable of being inserted into and advanced through a body lumen. FIG. 1 shows a typical catheter 10 which is advanced through the body along a guide wire 20. In order for guide wire 20 to pass through the catheter 10, the catheter or at least a portion thereof, defines a lumen 25 through which the guide wire 20 or other object may be advanced. Where the catheter 10 is



5 In the various embodiments shown, the combination of matrix 33 and the comparatively hard stripes 35 provides the tip 16 with improved flexibility for negotiating the tortuous confines of the vasculature but also with improved longitudinal rigidity for advancing the tip 16 with improved push-ability. As an example of the improved characteristics of the tip 16, in at least one tested embodiment, tip 16 has performance  
10 characteristics similar to a 74A rubber for purposes of radial expansion, and 60D for purposes of longitudinal elongation.

An additional benefit provided by the unique hybrid construction of tip 16 is that when the catheter 16 is used with a guide wire 20, the harder stripes 35 restrict the elasticity of the matrix 33 such that when the tip 16 travels along the guide wire 20 or when another catheter is passed through the opening 22, the tip 16 remains longitudinally rigid but is able to expand radially to allow for improved passage of the wire and/or catheter therethrough.

In the various embodiments show and described herein, the number of stripes 35 may vary from a single stripe 35 such as may be seen in FIG. 11 to several stripes as shown in FIGS. 2-10 and 12-13. In FIGS. 2-10 it may be seen that the stripes 35 may have a wide variety of orientations and positions relative to the matrix 33. The embodiments depicted in FIGS. 2-10 are just several examples of the configurations which may be utilized. One of skill in the art will recognize that the present invention is also directed to all other configurations, orientations and numbers of strips 35 which may be utilized with the matrix 33.

In FIG. 2, the stripes 35 appear to be a surface feature applied to the matrix 33. However, the stripes 35 may be partially imbedded within the matrix 33 or may share the same thickness as the matrix 33. The stripes 35 may be a braid of multiple fibers of hardened material 34 or may be a coating of hardened material 34. In the embodiment

shown the stripes 35 are uniformly distributed about the circumference of the tip 16, however other dispersement patterns are possible, examples of which are described in greater detail below. The stripes also extend the entire length of the tip 16 and may be configured to gradually reduce in width as they taper toward the end 24. Such a  
 5 configuration allows for uniform distribution of the first material 30 and second material 34 through out the length of the tip 16. However, if it is desired to provide a tip 16 with an end 24 which is harder or softer than the remaining portion of the tip 16, the width of the stripes 35 may be increased or reduced respectively.

In FIG. 3, the stripes 35 are imbedded within the matrix 33 and extend the  
 10 entire length of the tip 16. In the present embodiment, prior to being mounted on the stent delivery catheter the stripes 35 are oriented within the matrix 33 to be parallel to the longitudinal axis 13 of the tip 16.

In the embodiment shown in FIG. 4, a pair of stripes 35 are configured within the matrix 33 in opposing zig-zag patterns. The stripes 35 extend from a respective end 24  
 15 or 26 of the tip 16 and extend to a middle portion 15 of the tip 16 and then extend back toward the opposing end in an alternating pattern. In the embodiment shown, the zig-zag configured stripes 35 may be made up of individual members 51 whose ends are adjacent to one another. Alternatively, a single zig-zag stripe 35 may be employed which is a continuous stripe having a plurality of folds 41 at the tip ends 24 and 26 to provide the pattern shown.

20 In FIG. 5, the stripes 35 are also in a zig-zag pattern. The stripe 35 (or members 51 thereof) are angularly disposed relative to the longitudinal axis 13 of the sleeve 22. However, in FIG. 5 the stripes 35 (or lengths 51 thereof) fully extend from one end 24 of the tip 16 to the other 26.

In FIG. 6, an embodiment of the tip 16 is shown wherein each of the plurality  
 25 of stripes 35 have a random length which may or may not extend the entire length of the tip 16. Additionally, the individual stripes 35 may or may not be parallel to the longitudinal axis 13, and may have a completely random orientation relative to the longitudinal axis 13. It should also be noted that the stripes 35 may or may not be arranged in a uniform pattern such as is shown in the previously described embodiments.

In FIG. 7, a pair of strands 35 are shown in a double helix configuration wherein each strand 35 is helically disposed relative to the longitudinal axis 13 in opposing directions. In the embodiment shown in FIG. 8 a plurality of helically disposed strands 35 are imbedded in the matrix 33, wherein each of the strands 35 is oriented in the same  
5 direction.

In FIGS. 9-10 embodiments of the tip 16 are shown wherein the stripes 35 need not be completely imbedded within the matrix 33. In FIG. 9, the stripes 35 are engaged to the inner surface 100 of the matrix 33, whereas in FIG. 10 the stripes 35 are engaged to the outer surface 102 of the matrix 33. Whether engaged to the inside 100 or outside surface  
10 102, the matrix 33 may partially surround the stripes 35. Alternatively or in addition, the stripes 35 may be secured to the respective surface 100 and 102 in a variety of manners. For example, chemical adhesives, heat welding by laser or other means, chemical welding, etc, or other securing methods may all be used to secure the stripes 35 to the respective surfaces 100 and 102 of the matrix 33. However, in a preferred embodiment, the matrix material 30  
15 and the stripe material 34 are coextruded. It should also be noted that in an alternative embodiment one or more stripes may be engaged to the inner surface of the matrix, the outer surface of the matrix, and/or imbedded within the matrix or any combination thereof. Regardless of the position of the stripes within the matrix or on of its surfaces, the stripes may be positioned in any of the variety of configurations and orientations described herein.

20 In any of the embodiments described and/or depicted herein, the matrix material 30 may be selected from a wide variety of substances. For example, the matrix may include but is not limited to, one or more of the following substances: soft grade polyester/polyether elastomers such as Arnitel™ available from DSM Engineering, polyurethane-polyether polymers, such as Tecothane™ available from Thermedics, Inc.;  
25 polyester-polyurethanes, such as Pellethane™ sold by Dow Chemical; polyester-polyurethanes, such as Estane™ sold by BF Goodrich; polyether block amides (PEBA), such as Pebax™ available from Elf Atochem; and styrene-butadien-styrene triblock copolymers such as Kraton™ sold by Shell Chemical company. Other materials which may also be used in the production of the matrix material 30 include, but are not limited to styrenic block

[illegible]

- \_\_\_\_\_

33. The stripe 35 is made up of a plurality of interwoven fibers 40 which are woven together to form a braid structure 42. The braided configuration of the stripe 35 provides the sleeve 22 with a stripe or stripes 35 that may be substantially stronger than a single monofilament fiber 40, while maintaining the desired hardness and flexibility characteristics of the stripe material 34. As a result, tip 16 with one or more braids 42 of a given stripe material 34 shown will have improved longitudinal strength characteristics without a reduction in flexibility which may have resulted if a harder material 34 were used to form a monofilament stripe. In addition, where the stripe 35 is a braid 42 of several fibers 40, the individual fibers may be materials having different characteristics.

Not only are the stripes 35 variable in their characteristics, but the matrix 33 may also be provided in alternative forms. In FIG. 12, an embodiment of the tip 16 is shown wherein the matrix material 30 is actually a combination of materials. In the embodiment shown, the matrix 33 is a combination of an inner material 46 and an outer material 48, with a plurality of stripes 35 sandwiched in between. Providing the matrix 33 with a combination of materials may provide the tip 16 with even greater flexibility without substantial reductions in push-ability. For example, the inner material 46 may be a layer of hydrophobic elastomer such as a Siloxane-Polyurethane copolymer which has a relatively low surface friction and less tack, thereby providing the tip 16 with a reduced frictional interface between the inner surface 100 and a guide wire or catheter passing thereagainst. The outer material 48 may be comprised of a hydrophilic elastomer, such as hydrophilic polyurethane, which may provide the outer surface 102 of the tip 16 with wet lubricity characteristics when the outer surface is in contact with bodily fluids, such as when the catheter is advanced through a vessel. In addition to the example provided, it should be noted that the inner material 46 and the outer material 48 of the tip 16 may be provided with a wide variety of different or similar material combinations.

In FIG. 13 another embodiment is shown wherein the matrix 33 is comprised of three layers, with the stripes 35 completely imbedded within an intermediate layer 50, which is in turn sandwiched between the outer material 48 and inner material 46. Such an embodiment may be useful when the materials selected for the outer material 48 and inner

material 46 do not tend to readily bond together and an intermediate material 50 is used to provide a material which the outer material 48 and inner material 46 may be more readily bonded to. The matrix 33 is not limited to only the one, two or three layer configurations described herein, but may be embodied in a wide range of configurations having a plurality of layers of one or more materials.

The tip 16 may be provided in a wide range of shapes and sizes. The sleeves may have surface features such as dimples or troughs, or may have structural alterations such as through holes or ports, for altering the retraction characteristics of the tip. Tip 16 may include additional layers such as internal or external coatings, such as may be known in the art for improving the sleeve's as well as the catheter's performance.

In addition to being directed to the specific combinations of features claimed below, the invention is also directed to embodiments having other combinations of the dependent features claimed below and other combinations of the features described above.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each

be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below (e.g. claim 3 may be taken as alternatively dependent from claim 2; claim 5 may be taken as alternatively dependent on claim 3, claim 6 may be taken  
 5 as alternatively dependent from claim 3; claim 7 may be taken as alternatively dependent from claims 3, 5 or 6; etc.).